

The optimalistion of neuromuscular electrical stimulation in the treatment of swallowing disorders in multiple sclerosis

Gepubliceerd: 19-07-2018 Laatste bijgewerkt: 19-03-2025

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29473

Bron

NTR

Verkorte titel

NMES for dysphagia in MS

Aandoening

multiple sclerosis, dysphagia, swallowing disorders, NMES

multiple sclerose, dysfagie, slikproblemen, NMES

Ondersteuning

Primaire sponsor: Amsterdam UMC, VU University Amsterdam

Overige ondersteuning: Stichting MS Research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

A protocol to determine optimal electrode placement and neuromuscular electrical stimulation parameters for NMES for dysphagia in individual MS patients.

Toelichting onderzoek

Achtergrond van het onderzoek

This study will allow the investigation of the optimal parameters of neuromuscular electrical stimulation (NMES) in MS patients. We aim to develop a protocol for NMES to determine optimal electrode placement and stimulation parameters in dysphagia MS patients. The use of NMES as treatment may prevent complications and may increase Quality of Life in MS patients with dysphagia.

Doel van het onderzoek

The reported incidence of dysphagia in multiple sclerosis (MS) varies between 33% and 90% and is higher in more disabled patients. Dysphagia is associated with an increased risk of aspiration pneumonia, increase in health-care cost and increase in mortality and a decrease of quality of life (QOL). Patients with oropharyngeal swallowing problems are commonly referred to a speech-therapist for further assessment and treatment.

Limited evidence is available for treatment of dysphagia in MS. A significant decrease of dysphagia in MS after treatment with neuromuscular electrical stimulation (NMES) was found, but in other studies the results of the effect of NMES on dysphagia were inconsistent. Therefore, the need for research into the optimal parameters for the application of NMES is clear.

Onderzoeksopzet

One timepoint of measurement: ultrasonography and NMES will be used at the same day in approximately 1 hour.

Onderzoeksproduct en/of interventie

Ultrasonography will be used to determine the location and assess the morphology of the hyoid muscles.

Electrical stimulation will be used to stimulate the hyoid muscles. Simultaneously, ultrasonography will be used to guide optimal electrode placement and stimulation characteristics.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- > 18 years of age
- confirmed diagnosis of MS
- dysphagia characterized by incomplete hyoid movement

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- other neurological disorders
- obstruction of nasal passage
- significant cognitive deficits (has to be able to follow instructions during endoscopy and give feedback on sensing stimulation or pain in head and neck)
- medically not stable enough to participate in endoscopy

- radiotherapy or oncology in head/neck area

- in case of heart problems, metal implants in head/neck area, inflamed skin, implanted stimulators or electronic devices, participation should be evaluated by a medical doctor

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-08-2018
Aantal proefpersonen:	25
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	19-07-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47927

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7182
NTR-old	NTR7373
CCMO	NL62007.029.17
OMON	NL-OMON47927

Resultaten